PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61L 15/22, A61M 35/00, A61K 9/70

A1

(11) International Publication Number: WO 96/34633

(43) International Publication Date: 7 November 1996 (07.11.96)

(21) International Application Number: PCT/SE96/00567

(22) International Filing Date: 2 May 1996 (02.05.96)

(30) Priority Data:
9501670-5 5 May 1995 (05.05.95) SE

(71) Applicant *(for all designated States except US)*: PERSTORP AB [SE/SE]; S-284 80 Perstorp (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: WESTRIN, Bengt [SE/SE]; Iliongränd Q:336, S-224 71 Lund (SE).

(74) Agent: STENBERG, Yngve; Perstorp AB, S-284 80 Perstorp (SE).

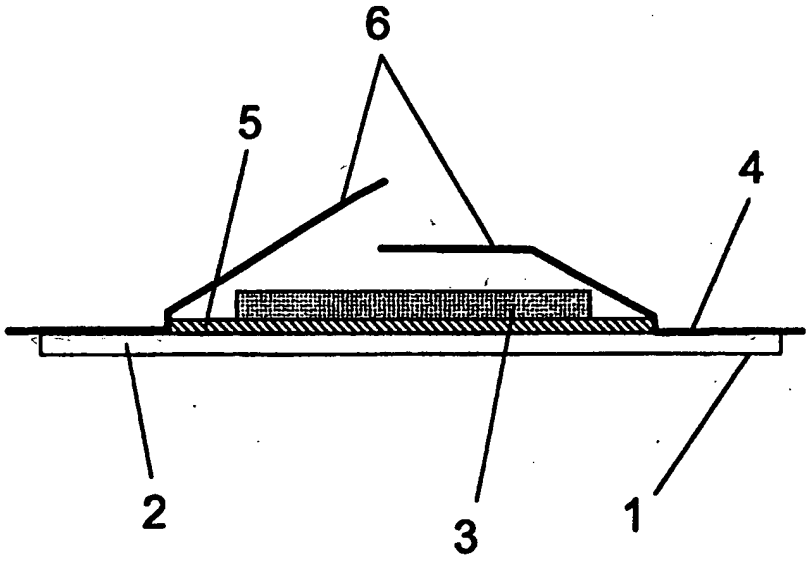
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: DRESSING SET

(57) Abstract

A dressing set (1) comprising a non-occlusive backing (2), which backing (2) optionally has at least one adhesive side (4), a reservoir (3), which reservoir (3) in area is smaller than or at most equal to the backing (2) and which reservoir (3) comprises one or more layers and at least one pharmaceutically active compound, and optionally one or more peel strips, release papers (6) or similar arrangement protecting the reservoir (3) and/or the optional adhesive side (4) of said backing (2). A foil (5) having an area being larger than or at least equal to the area of the reservoir (3) is located between the reservoir (3) and the backing (2), which foil (5) consists of at least one hydrophilic or hydrophilized polymer. The foil (5) is in a dry, moisture-free state substantially occlusive, and after moisture absorption substantially non-occlusive.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

DRESSING SET

The present invention refers to a dressing set primarily intended as a wound dressing and for transdermal drug delivery, so called TDDS (Transdermal Drug Delivery Systems) and/or similar pharmaceutical and medical applications. The dressing set comprises a hydrofil barrier located between the drug reservoir and the backing of said set. The barrier is in a dry, moisture free, state occlusive and after moisture absorption non-occlusive.

A dressing set normally comprises an adhesive backing, a reservoir such as a compress, swab, matrix or similar having one or more layers and containing at least one pharmaceutically active compound, such as a drug or an antiseptic, and one or more peel strips, release papers or the like protecting the adhesive backing and/or the reservoir.

Dressing sets are used in a number of applications including wound dressings, antiseptic and chemotherapeutic dressings. Wound dressings include compresses or swabs containing one or more pharmaceutical compounds, which compresses are attached onto a patient by means of adhesive tapes or plasters. Application areas of TDDS include for instance treatment of angina pectoris, diabetes and motion sickness, and are used in smoking cessation therapy. The use of TDDS is rapidly growing and the drug containing reservoirs are gradually improved with pendant increased security and thus a more controlled drug delivery. The use and development of various TDDS are in detail described in "Transdermal Drug Delivery - volume 35 - Development Issues and Research Initiatives" edited by J. Hadgraft and R.H. Guy and issued by Marcel Dekker Inc., New York, USA.

A major problem during storage and use of dressing sets comprising a reservoir, such as a compress, a matrix or similar, containing for instance one or more drugs, is migration or other type of leakage of the active compound into or through the backing material. This implies a reduced storage time, an uncertain amount of active compound available for the actual treatment, unfavourable chemical and/or physical interactions between the active compound and the backing material and handling as well as health hazards due to drug impregnated or otherwise drug containing packages. The risk of incorrect or hazardous treatment as well as said health hazards, related to the handling of for instance drug containing packages, is obvious. Migration or other leakage can be difficult to observe unless the active compound give rise to discoloration, which per se can create problems of psychological and/or cosmetic art.

A solution to above problems is for instance a dressing set comprising an occlusive backing. This is, however, in most cases unacceptable from a medical point of view, especially in treatment of wounds requiring a non-occlusive dressing. An occlusive backing prevents the necessary ventilation of the wound and increases the moisture in and on the skin covered by the dressing thus causing maceration.

Dressing sets comprising an occlusive barrier located in for instance a pocket or the like between a drug reservoir and a non-occlusive backing, is also known. The barrier is in such a case removed before applying the dressing set, whereby a non-occlusive dressing is obtained. The solution to above problems give, however, rise to certain drawbacks, such as production obstacles, adhesion between the reservoir and/or the backing and the barrier with resulting difficulties in removing said barrier, and unnecessary handling of the dressing possibly resulting in contamination thereof.

Disclosed problems and drawbacks have quite unexpectedly been solved or substantially reduced by the present invention, which relates to a dressing set, primarily intended for wound dressings but also useful for TDDS and other applications including dressing sets. The dressing set according to the present invention comprises

i) a substantially non-occlusive and preferably adhesive backing,
ii) a compress, swab, matrix or similar reservoir comprising one or more layers and at least one pharmaceutically active compound,
iii) one or more peel strips, release papers or the like, and
iv) a foil having an area being larger or at least equal to the area of said reservoir, which foil is located between said reservoir and said backing

The foil is made of at least one hydrophilic or hydrophilized polymer and is in a moisture free state substantially occlusive and after absorption of moisture substantially non-occlusive.

The moisture free, that is the dry and unused, occlusive foil works during storage of the dressing set as a barrier towards migration and other type of leakage into or through the backing. The active compound in the reservoir can thus be kept at a substantially constant level, whereby the storage time can be prolonged and problems related to uncertainty regarding available amount of active compound or compounds can substantially be eliminated. Handling and health hazards related to drug impregnated or otherwise drug containing packages, as may be the result of migration or leakage, are furthermore reduced or eliminated. The dressing of the present invention also opens the possibility of including into the reservoir compounds now regarded as impossible to include due to discussed problems.

The foil will when used, that is applied onto the skin of a patient, absorb moisture from or via the skin and thus obtain non-occlusive properties, whereby the entire dressing set will be substantially non-occlusive. The non-occlusive properties are as previously disclosed of vital importance in for instance the treatment of various wounds and other therapies requiring ventilation or air supply in general.

The present invention facilitates the productions of or even makes it possible produce dressing sets intended for antiseptic and chemotherapeutic treatment of wounds. The conventionally used drug containing compresses, swabs and the like are advantageously replaced by a dressing set according to the present invention, especially when the pharmaceutically active compound without a barrier is likely to migrate through, interact with or give rise to discoloration of a non-occlusive backing material. A dressing set facilitates, in comparison to compresses or the like, both handling and therapeutic treatment.

Most hydrophilic or hydrophilized polymers, being non-occlusive in a dry state and being pharmaceutically acceptable as well as inert to the pharmaceutically active compound or compounds, can be used to produce the foil included in the dressing set of the present invention. Especially suitable and in various embodiments preferred polymers can be exemplified by hydrophilized polyurethanes, agar, agarose and/or derivatives thereof or by crosslinked dextrine, starch, dextran, cellulose, poly(vinyl alcohol), poly(acrylamide), poly(vinyl pyrrolidone) and/or derivatives thereof.

The dressing set of the present invention comprises preferably one or more peel strips, release papers or the like, which preferably are made of for example a siliconized pharmaceutically acceptable polymer foil or siliconized paper.

The dressing set of the present invention is especially suitable for wound dressings having a reservoir containing one or more antiseptic and/or chemotherapeutic compounds, such as cadexomer iodine, framycetin, fusidic acid and/or derivatives thereof as well as mixtures thereof and therewith. Further suitable application areas of the dressing set according to the present invention include TDDS comprising for example nitro-glycerine, nicotine, scopolamine, œstrogenes and/or prostaglandines.

These and other objects and the attendant advantages will be more fully understood from the following detailed description, taken in conjunction with appended Figures, wherein like reference numerals have been applied to like parts throughout the Figures and wherein:

- Figure 1 is flat view of an embodiment of a dressing set according to the present invention. The dressing set is shown from a side comprising a drug reservoir under which a foil barrier is located.
- Figure 2 is a side of the same embodiment of a dressing set as shown in Figure 1.

Figure 1 shows a flat view of an embodiment of a dressing set 1 according the present invention. The dressing set 1 comprises a non-occlusive backing 2 having one adhesive side 4, in this case turned towards the viewer, a reservoir 3 of type compress comprising a pharmaceutically active compound and a foil 5 located between the reservoir 3 and the backing 2. The foil 5 consists of a hydrophilized polyurethane being occlusive is in a dry, moisture free state, whereby migration or leakage of the pharmaceutically active compound in the reservoir 3 into or through the backing 2 is prevented.

Figure 2 shows in a side view the same embodiment of a dressing set 1 according to the present invention as Figure 1. The dressing set accordingly comprises a non-occlusive backing 2 having one adhesive side 4, a drug reservoir 3 and a foil 5, made from a hydrophilized polyurethane and located between the reservoir 3 and the adhesive side 4 of the backing 2. The dressing set 1 also includes two release papers 6 made of siliconized paper.

The various parts shown in Figures 1 and 2 are not entirely according to scale. Some parts are for the sake of clarity enlarged or reduced. Optional peel strips or release papers 6 are for reason of simplicity not included in Figure 1.

While a particular embodiment of the invention has been shown, it will be understood, of course, that the invention is not limited thereto since many modifications may be made, and it is, therefore, contemplated to cover by the appended claims any such modifications as fall within the true spirit and scope of the invention.

CLAIMS

1. A dressing set (1) comprising a non-occlusive backing (2), which backing (2) optionally has at least one adhesive side (4), a reservoir (3), which reservoir (3) in area is smaller than or at most equal to the backing (2) and which reservoir (3) comprises one or more layers and at least one pharmaceutically active compound, and optionally one or more peel strips, release papers (6) or similar arrangement protecting the reservoir (3) and/or the optional adhesive side (4) of said backing (2)
   characterized in, that
   a) a foil (5) having an area being larger than or at least equal to the area of the reservoir (3) is located between the reservoir (3) and the backing (2),
   b) the foil (5) consists of at least one hydrophilic or hydrophilized polymer,
   c) the foil (5) in a dry, moisture free state is substantially occlusive, and
   d) the foil (5) after moisture absorption is substantially non-occlusive.

2. A dressing set (1) according to Claim 1
   characterized in, that
   the foil (5) consists of at least one hydrophilized polyurethane.

3. A dressing set (1) according to Claim 1
   characterized in, that
   the foil (5) consists agar, agarose and/or at least one derivative thereof.

4. A dressing set (1) according to Claim 1
   characterized in, that
   the foil (5) comprises of at least one polymer selected from the group consisting of crosslinked dextrine, starch, dextran, cellulose and derivatives thereof.

5. A dressing set (1) according to Claim 1
   characterized in, that
   the foil (5) comprises of at least one polymer selected from the group consisting of crosslinked poly(vinyl alcohol), poly(acrylamide), poly(vinyl pyrrolidone) and derivatives thereof.

6. A dressing set (1) according to any of the Claims 1-5
   characterized in, that
   the dressing set (1) comprises at least one peel strip or release paper (6) made of a siliconized pharmaceutically acceptable polymer or siliconized paper.

7. A dressing set (1) according to any of the Claims 1-6
characterized in, that
the reservoir (3) is made up of at least one compress or swab.

8. A dressing set (1) according to any of the Claims 1-7
characterized in, that
the reservoir (3) comprises at least one pharmaceutically active compound or preparation having antiseptic and/or chemotherapeutic effect.

9. A dressing set (1) according to any of the Claims 1-8
characterized in, that
the reservoir (3) comprises at least one pharmaceutically active compound selected from the group consisting of cadexomer iodine, framycetin, fusidic acid and derivatives thereof.

10. A dressing set (1) according to Claim 9
characterized in, that
the dressing set (1) is a wound dressing.

11. A dressing set (1) according to any of the Claims 1-8
characterized in, that
the reservoir (3) comprises at least one pharmaceutically active compound selected from the group consisting of nitro-glycerine, nicotine, scopolamine, œstrogenes, prostaglandines and derivatives thereof.

12. A dressing set (1) according to Claim 11
characterized in, that
the dressing set (1) is a so called Transdermal Drug Delivery System (TDDS).

Fig. 1

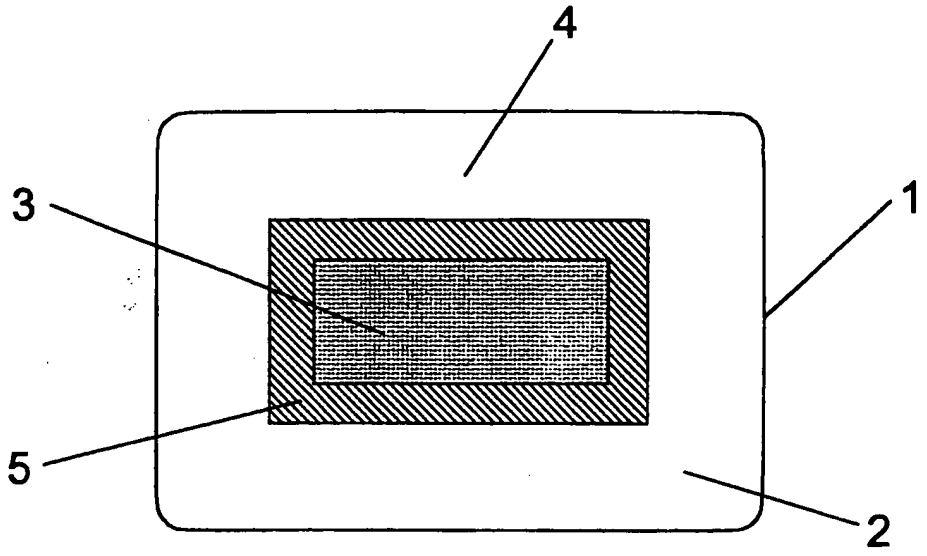
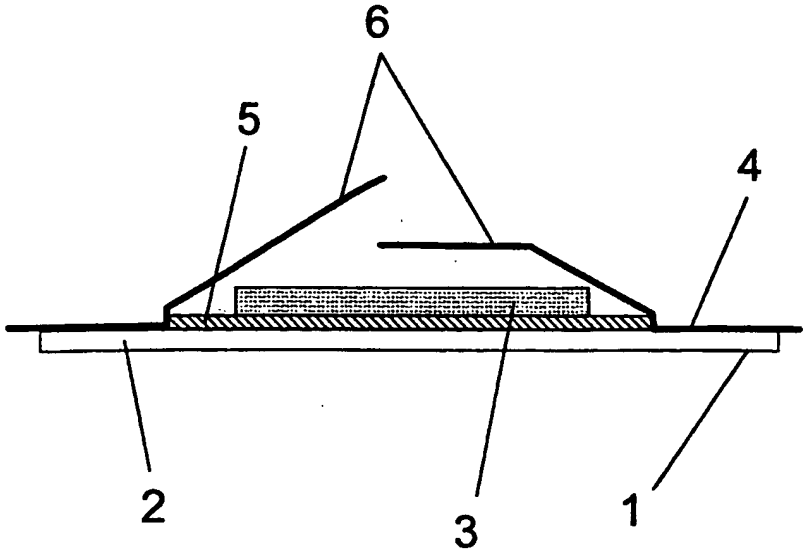


Fig. 2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 96/00567

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 15/22, A61M 35/00, A61K 9/70
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61L, A61K, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0249343 A1 (ALZA CORPORATION), 16 December 1987 (16.12.87), column 3, line 56 - column 4, line 18; column 8, line 13 - line 29	1-12
A	US 5411740 A (EUN S. LEE ET AL), 2 May 1995 (02.05.95), column 5, line 24 - column 6, line 12, figures 2-3	1-12

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 June 1996	'22 -07- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Hans Bäckström Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.
PCT/SE 96/00567

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A1- 0249343	16/12/87	SE-T3- 0249343	
		AU-B,B- 590921	23/11/89
		AU-A- 7365387	17/12/87
		CA-A- 1297369	17/03/92
		DE-A- 3775830	20/02/92
		JP-A- 62298520	25/12/87
		KR-B- 9409524	14/10/94
		PT-B- 85044	31/03/94
		US-A- 5141750	25/08/92
		US-A- 5284660	08/02/94
		ZA-A- 8704129	08/12/87
US-A- 5411740	02/05/95	US-A- 5500222	19/03/96
		AU-B- 666735	22/02/96
		AU-A- 4247393	13/12/93
		CA-A- 2132865	25/11/93
		FI-A,D- 945311	11/11/94
		JP-T- 8502952	02/04/96
		NO-A,D- 944249	14/11/94
		WO-A- 9323025	25/11/93
		ZA-A- 9303349	15/06/94